AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for detecting a target nucleic acid having a target sequence in a sample, comprising the steps of:

(a) mixing a first probe comprising a nucleic acid which has a specific region having a sequence complementary to the target sequence and a nonspecific region having a sequence that is not complementary to the target sequence of the target nucleic acid; and a second probe comprising a nucleic acid which has a first region that is complementary to at least a portion of the nonspecific region of the first probe, a loop region that does not have a sequence complementary to the first probe, and a second region that is complementary to at least a portion of the specific region of the first probe which is complementary to the target sequence, wherein the nucleic acid of the second probe is labeled with a labeling material generating a signal by which formation of the loop can be detected;

~~, the loop region~~(b) forming ~~a~~ the loop in the loop region when ~~it~~ the second probe is annealed with the first probe~~, wherein the nucleic acid of the second probe is labeled with a labeling material generating a signal by which formation of the loop can be detected;~~, thereby quenching the signal from the labeling material in the absence of the target;

(c) ~~and a~~adding the sample, whereby the target nucleic acid in the sample anneals with the first probe~~under conditions in which the first probe and the second probe are annealed and the first probe and the target nucleic acid are annealed~~; and

(~~b~~d) detecting a ~~change~~ higher intensity in the signal of the labeling material in the presence of the target, thereby detecting the target nucleic acid, wherein the signal is quenched when the first probe and the second probe are annealed and not quenched when the first probe and the second probe are not annealed, in the presence of the target.

2. (Previously presented) The method according to claim 1, wherein the second region of the second probe is shorter than the specific region of the first probe.

3. (Previously presented) The method according to claim 1, wherein the labeling material comprises a fluorescent material and a quencher that quenches a fluorescence of the fluorescent material when the quencher is near the fluorescent material, arranged so as to sandwich the loop region, with the fluorescence of the fluorescent material being quenched by the quencher when the first probe and the second probe are annealed to form the loop and not quenched when the first probe and the second probe are not annealed.

4. (Previously presented) The method according to claim 1, wherein the detection of the change in the signal is performed quantitatively, thereby quantifying the target nucleic acid.

5. (Currently amended) A kit for detecting a target nucleic acid having a target sequence in a sample, comprising:

a first probe comprising a nucleic acid which has a specific region having a sequence complementary to the target sequence and a nonspecific region having a sequence that is not complementary to the target sequence of the target nucleic acid; and

a second probe comprising a nucleic acid having a first region that is complementary to at least a portion of the nonspecific region of the first probe, a loop region that does not have a sequence complementary to the first probe, and a second region that is complementary to at least a portion of the specific region of the first probe which is complementary to the target sequence, the loop region forming a loop when it is annealed with the first probe, wherein the nucleic acid of the second probe is labeled with a labeling material generating a signal by which formation of the loop can be detected,

wherein the signal is quenched when the first probe and the second probe are annealed and not quenched when the first probe and the second probe are not annealed, in the presence of the target.

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

Two proposed amendments to claim 1 and a draft of arguments was faxed to Examiner Shaw prior to the interview.

Identification of Claims Discussed

Claim 1

Identification of Prior Art Discussed

Weston, et al. ((US 6,391,593)

Proposed Amendments

A first proposed amendment introduced a negative limitation that "the second probe does not bind to the target" finding basis in Figure 1. However, the PTO did not think that Figure 1, alone or taken with the specification, provided sufficient support for the proposed amendment.

Regarding a second proposed amendment, the Examiners felt that the Weston patent still anticipated the amended claim.

Principal Arguments and Other Matters

Applicant's representative argued primarily the following points:

1) Applicant's invention differs from Weston, et al in that Weston, et al teach a tri-molecular binding whereas Applicant's method is directed to a competitive binding where probe 1 binds either to probe 2 or to the target.

2) Weston, et al. teach that both probes bind to the target and that binding is in an adjacent manner. In Applicant's invention, only one probe binds to the target and there is no adjacent binding of the two probes.

3) Applicant teaches an increase in signal when the target binds to the first probe only. Weston, et al. requires binding of two probes to the target for generation of a nucleotide that is detected. To the extent that Weston, et al. discusses the possibility of a change in intensity of a label, Weston, et al. teaches that signal decreases upon target binding, not an increase as claimed by Applicant.

4) Applicant teaches that probe 1 and 2 anneal to each other, thereby forming a loop which quenches the signal. Weston, et al. teach prevention of the annealing of probes 1 and 2 in

the absence of the target. While Weston, et al. teach a loop, the formation of the loop is not tied to any change in signal.

Results of Interview

The PTO suggested amendment of claim 1 so that it was more clear what was going on, i.e., spell out what happens if target is present and what happens if target is absent. The claim under examination only recites "mixing" and "determining" steps which were deemed insufficient to distinguish the claimed invention from Weston, et al. by the PTO. The PTO also suggested filing of an RCE so that a new search could be performed on the amended claims.